

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/598,604	LAMBL, BARBARA B.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ginny Portner	1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/28/05.
2. ☒ The allowed claim(s) is/are 1,5-7,9,10,12,14,15,17,19-21 and 35-37.
3. ☒ The drawings filed on 21 June 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|   | 9. <input type="checkbox"/> Other _____   |

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Paul Clark, Registration number 30,162 on Thursday, April 28, 2005.

The application has been amended as follows:

1. (Currently Amended) A biologically pure culture of a single-celled organism, Spiky Rotating Cells (SPR), having all of the characteristics of the deposited single-celled organism having the accession number ATCC PTA-2129, wherein said organism causes disease in humans and comprises the following biological characteristics: (i) provisional classification as a protozoan, (ii) a spherical shape measuring approximately 7-8  $\mu\text{m}$  as a solitary single-celled organism, (iii) a refractile cell membrane, (iv) multiple circumferential spiky projections of the cell membrane, (v) rotatory motility, (vi) periodic clustering behavior to form colonies, and (vii) existence in an extracellular environment.

5. (Currently Amended) A method of diagnosing an SPR infection in a human patient, said method comprising the steps of:

a) obtaining a sample from said patient; and

b) testing said sample for the presence of an organism, having all of the characteristics of the deposited single-celled organism having the accession number ATCC PTA-2129, that causes disease in humans, said organism having the following biological characteristics: (i) provisional classification as a protozoan, (ii) a spherical shape measuring approximately 7-8  $\mu\text{m}$  as a solitary single-celled organism, (iii) a refractile cell membrane, (iv) multiple circumferential spiky

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projections of the cell membrane, (v) rotatory motility, (vi) periodic clustering behavior to form colonies, and (vii) existence in an extracellular environment.

17. (Currently Amended) A method of treating an SPR infection in a patient, said method comprising the steps of:

a) diagnosing said SPR infection, wherein the organism causing said SPR infection causes disease in human and comprises all of the characteristics of the deposited single-celled organism having the accession number ATCC PTA-2129 and the following biological characteristics: (i) provisional classification as a protozoan, (ii) a spherical shape measuring approximately 7-8  $\mu\text{m}$  as a solitary single-celled organism, (iii) a refractile cell membrane, (iv) multiple circumferential spiky projections of the cell membrane, (v) rotatory motility, (vi) periodic clustering behavior to form colonies, and (vii) existence in an extracellular environment; and

b) upon obtaining a positive diagnosis in step a), administering to said patient an SPR inhibiting amount of an anti-SPR agent selected from the group consisting of itraconazole, ofloxacin and metronidazole.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp  
May 1, 2005

  
**LYNETTE R. F. SMITH**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**